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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/044,842	01/11/2002	Issam Raad	UTSC:669US	7921

7590 02/12/2008

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EXAMINER	
MCKANE, ELIZABETH L	

ART UNIT	PAPER NUMBER
1797	

MAIL DATE	DELIVERY MODE
02/12/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/044,842	RAAD ET AL.	
	Examiner	Art Unit	
	Leigh McKane	1797	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35,69,74-77,91-111 and 114-134* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35, 69, 74-77, 91-111, 114-134* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 69, 74, 98, 103, 124-126, 128, 129, and 134 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Specifically, while the original disclosure may support specific claimed ratios, it does not support claims directed to a critical claimed range. The original disclosure lacks any examples, etc. which would support the newly claimed ranges. Furthermore, tests presenting evidence showing unexpected results or properties in the newly claimed range and the unexpected results or properties were not described in the original specification, this evidence would further support the conclusion that the applicant was not in possession of the invention as claimed at the time the invention was filed.

Furthermore, as to the recitation of D&C Yellow No.1 in claims 69 and 74, this particular dye could not be found in any listing found on the FDA website or in CAS Registry.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 103, 104, 108, 130, and 134 are rejected under 35 U.S.C. 102(b) as being anticipated by Cid (ES 2061407).

Cid teaches a method of disinfecting a scalp (organic surface) comprising applying a composition including chlorhexidine in an amount of 0.2-8% and brilliant green (green malachite) in an amount of 0.01-0.1%.

5. Claims 103, 104, and 131-134 are rejected under 35 U.S.C. 102(e) as being anticipated by Pelerin (US 2002/0009693).

Pelerin discloses the use of gentian violet in a chlorhexidine-containing disinfecting composition to indicate to the user where the composition has been applied. See paragraph [0012]; Table 1, example 2. The chlorhexidine is used in an amount of up to 10%, preferably 0.5-5%. The gentian violet is used in an amount of up to 5%, preferably 0.5-2%. These concentrations fall within the claimed ratios.

6. Claims 109-111 are rejected under 35 U.S.C. 102(b) as being anticipated by Pelerin (US 2002/0009693).

Pelerin discloses a method of disinfecting a wound (exposed dental root) by applying a composition containing gentian violet and chlorhexidine thereto. See paragraphs [0009], [0012], and Table 1, Example 2.

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Fenn et al. (GB 2007096) in view of Dodd et al. (US 6,344,218).

Fenn et al. teaches a basic reagent, chlorhexidine, bound to an anionic dye. See page 1, lines 65-77; lines 114-117. Fenn et al. is silent with respect to using gendine as the basic reagent.

Dodd et al., however, discloses that it was known in the art at the time of the invention to employ antimicrobial mixtures of gentian violet and chlorhexidine (e.g. gendine). It would have been obvious to use a mixture of chlorhexidine and gentian violet as the antimicrobial of Fenn et al., as both are disclosed by Dodd et al. to be 'fast acting' and each would bring unique antimicrobial effectiveness to the composition. As gentian violet is also cationic, it would intrinsically bond with the anionic dye in the same manner as the chlorhexidine.

10. Claims 69, 74-77, 91-96, 99, 100, 114-119, 121, 122, and 124-129 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra et al. (WO 00/65915) in view of Pelerin.

Luthra et al. teaches a method of disinfecting a medical device by applying a composition containing chlorhexidine thereto. See col.1, lines 16-23; page 4, line 26; page 5, lines 21-23. The medical device may be fabricated from a polymeric material such as silicone (page 1, lines 25-27). Luthra et al. fails to disclose including a dye in the composition.

However, Pelerin discloses the use of gentian violet in a chlorhexidine-containing disinfecting composition to indicate to the user where the composition has been applied. See paragraph [0012]. The chlorhexidine is used in an amount of up to 10%, preferably 0.5-5%. The gentian violet is used in an amount of up to 5%, preferably 0.5-2%. These concentrations fall within the claimed ratios. It would have been obvious to one of ordinary skill in the art at the time of the invention to add gentian violet to the composition of Luthra et al. in order to provide a means of indicating wherein the composition has been applied to the medical device, thereby assuring the practitioner that the device has been completely treated. Moreover, one would have found it obvious to maintain the relative concentrations disclosed by Pelerin as being successful in a disinfecting composition.

Since the medical devices of Luthra et al. include catheters, blood bags, and dialysis membranes - all of which are fluid-contacting devices – the composition of Luthra et al. with Pelerin would necessarily be effective to disinfect pathogens contained within fluids. See page 1, line 20. It is deemed obvious to apply the disinfecting function disclosed by Luthra et al. to disinfect other fluid pathogen sources.

While Luthra et al. primarily discloses use of the composition to coat polymeric medical devices, Luthra et al. generally teaches that the "term medical device as used herein is intended to encompass the full range of devices for intimate contact with the human or other mammalian body, or with the corresponding body fluids". Given this teaching, one of ordinary skill in the art would have found it obvious to apply the method of Luthra et al. to silk sutures as being an article in intimate contact with the human body and corresponding body fluids.

11. Claims 97, 101, 102, 120, and 123 are rejected under 35 U.S.C. 103(a) as being unpatentable over Luthra et al. and Pelerin as applied to claims 69, 74, 118, and 122 above, and further in view of Ibsen et al. (US 4,204,978).

The combination *supra* discloses gentian violet as the dye. The use of brilliant green is not disclosed. Ibsen et al. discloses the equivalence of brilliant green (malachite green) and gentian violet as dye indicators. Thus, it would have been obvious to one of ordinary skill in the art to substitute the brilliant green of Ibsen et al. for the gentian violet of Luthra et al. with Pelerin as the results would have been expected.

12. Claim 98 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin in view of Ibsen et al..

Pelerin discloses the use of gentian violet in a chlorhexidine-containing disinfecting composition to indicate to the user where the composition has been applied. See paragraph [0012]. The chlorhexidine is used in an amount of up to 10%, preferably 0.5-5%. The gentian violet is used in an amount of up to 5%, preferably 0.5-2%. These concentrations fall within the claimed ratios. Pelerin further teaches that the composition is "typically dabbed or dropped" onto the specific site. The dental art typically uses swabs and/or gauze for dabbing and a dropper

(medical device) for dropping. The contact of the composition of Pelerin with these articles would intrinsically meet the claim limitation. Pelerin does not disclose the use of brilliant green as the dye. Ibsen et al. discloses the equivalence of brilliant green (malachite green) and gentian violet as dye indicators in dental compositions. Thus, it would have been obvious to one of ordinary skill in the art to substitute the brilliant green of Ibsen et al. for the gentian violet of Pelerin as the results would have been expected.

13. Claim 105 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin as applied to claim 103 above, and further in view of Mantelle (US 6,562,363).

Pelerin fails to teach clofoctol as the antibacterial agent. However, Mantelle discloses the known use of clofoctol as an antibacterial agent. See col.14, line 20. It would have been obvious to use other known antibacterial agents in the composition of Pelerin where the results are not unexpected.

14. Claim 106 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin as applied to claim 103 above, and further in view of Darouiche (US 5,853,745).

Pelerin fails to teach chloroxylenol as the antibacterial agent. Darouiche evidences the known use of chloroxylenol as an effective antimicrobial agent which "is minimally affected by organic matter" (col.6, lines 34-41). For this reason, one would have found it obvious to use chloroxylenol as the antibacterial agent of Pelerin.

15. Claim 107 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin as applied to claim 103 above, and further in view of Curtis et al. (US 5,209,251).

Pelerin fails to teach triclosan as the antibacterial agent. Curtis et al. discloses that triclosan is an equivalent of chlorhexidine in a dental composition. See claim 9. Thus, it is deemed obvious to substitute one for the other in the composition of Pelerin.

16. Claim 108 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pelerin as applied to claim 103 above, and further in view of Ibsen et al.

Pelerin does not disclose the use of brilliant green as the dye. Ibsen et al. discloses the equivalence of brilliant green (malachite green) and gentian violet as dye indicators in dental compositions. Thus, it would have been obvious to one of ordinary skill in the art to substitute the brilliant green of Ibsen et al. for the gentian violet of Pelerin as the results would have been expected.

Response to Arguments

17. Applicant's arguments with respect to the claims have been considered but are moot in view of the new ground(s) of rejection.

18. The Declarations filed 31 October 2007 have been considered. However, in view of the new grounds of rejection, they are deemed insufficient.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leigh McKane/
Primary Examiner, Art Unit 1797

elm
3 February 2008